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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21DA; Docket No. CDC-2021-0011]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Phased Approach to the Resumption of Passenger Operations. The proposed collection outlines a number of information collection activities required as part of the process to returning to passenger operations.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0011 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Phased Approach to the Resumption of Passenger Operations – Existing Collection in use without an OMB Control Number –

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Framework for Conditional Sailing Order published in the *Federal Register* on November 4, 2020 prohibits a cruise ship operator from commencing or continuing any regular passenger operations without a COVID-19 Conditional Sailing Certificate issued by HHS/CDC. This information collection request outlines the reporting and document retention requirements that are part of a phased approach to resuming passenger operations.

Per CDC's Framework for Conditional Sailing Order, cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order (NSO) or voluntarily withdrew their ships, must have a NSO response plan deemed complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy. In addition, cruise ship operators must continue to follow their cruise lines' complete, accurate, and acknowledged NSO response plans per the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (i.e., "No Sail Order response plan"), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)).

The Framework for Conditional Sailing Order introduced a phased-in approach to the resumption of cruise ship passenger operations. This Framework Order details the requirements of the initial phase, which focuses on mass testing of crew and building the laboratory capacity needed to test both crew and future passengers.

The Second Phase of the Framework Order focuses on preparation for simulated voyages. As required under the CSO, a cruise ship operator's agreement with U.S. port authorities and local health authorities must include the following elements: (1) a port agreement between the cruise ship operator and port authority to determine the number of cruise ships operating out of any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak; (2) medical care agreements between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical instructions and orders; and (3) housing agreements between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and close contacts, identified from the day of embarkation through disembarkation for each voyage. This Phase also includes a shift in reporting requirements using the CDC (EDC) form previously approved in OMB Control Number 0920-0134 Foreign Quarantine Regulations.

Starting in this phase, the form will be required from cruise ships on a daily, rather than weekly, rhythm.

Phase 2B of the Framework Order focuses on simulated voyages with volunteers playing the role of passengers to test cruise ship operators' ability to mitigate COVID-19 risk. A cruise ship operator must submit a Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate to conduct a simulated voyage at least 30 calendar days prior to the voyage. CDC will issue additional technical guidance outlining the specific areas that may be inspected and corresponding recommendations.

Following each simulated voyage, the cruise ship operator must document any deficiencies in its health and safety protocols through an "after-action" report and address how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. This after-action report must also include test results for any volunteer passengers or crew on the simulated voyage.

As a condition of applying for a COVID-19 Conditional Sailing Certificate (Phase 3), a cruise ship operator must have successfully conducted a simulated voyage or series of simulated voyages demonstrating the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship. The CDC COVID-19 Conditional Sailing Certificate Application form includes certain minimum requirements that must be met prior to a restricted voyage and burden for these requirements is

outlined in section 12 below. These documents must be submitted 60 days prior to any proposed restricted voyage. If the Certificate is denied, revoked, or suspended, a cruise ship operator may submit a written appeal of a denial of its application for a COVID-19 Conditional Sailing Certificate or a revocation or suspension of its COVID-19 Conditional Sailing Certificate.

Compliance with the Framework for Conditional Sailing Order, beyond the information collections outline above, are primarily associated with the testing required, both onshore and onboard. This estimate includes the cost of onboard testing and lab equipment and maintenance on the ship.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Cruise ship operator	No Sail Order Response Plan	5	1	2400/60	200
Cruise ship operator	Request for Embarkation of Essential Crew and Contractors submitted to USCG	5	1	10/60	1
Cruise ship operator	CDC an Attestation for Non-Commercial Travel of Disembarking Crew for Cruise Ship Operators During the No Sail Order	5	5	15/60	7

Cruise ship operator	Virtual Implementation Checks	5	2	75/60	13
Cruise ship operator	Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (Daily)	130	365	15/60	11,863
Cruise ship operator	CLIA Certified Laboratory Information – Onshore	20	25	5/60	42
Cruise ship operator	Approval of Onboard COVID-19 Testing Instrument	20	25	5/60	42
Cruise ship operator	Request for Embarkation of Essential Crew and Contractors	130	5	10/60	109
Cruise ship operator	Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC's Framework for Conditional Sailing Order (CSO)	130	5	15/60	163
Cruise ship operator	Agreement with Health Care Organization with signoff from Local Health Authorities	130	1	600/60	1,300
Cruise ship operator	Agreement with Port of Entry with signoff from Local Health Authority	130	1	600/60	1,300

Cruise ship operator	Agreement with Housing Facility with signoff from Local Health Authority	130	1	600/60	1,300
Cruise ship operator	Request for Embarkation of Non-Essential Crew and contractors	130	1	10/60	10
Cruise ship operator	Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate	130	1	600/60	1,300
Passenger (3rd party disclosure)	Informed Consent and Medical Certification with no pre-existing conditions for Simulated Voyage	39000	1	75/60	48,750
Cruise shop operator	Remote and In-person Inspections	130	1	120/60	260
Cruise shop operator	After Action Report, Simulated Voyage	130	1	600/60	1,300
Cruise ship operator	COVID-19 Conditional Sailing Certificate Application	130	1	600/60	1,300
Cruise ship operator	Remote and In-person Inspections	130	1	120/60	260
Total					69,530

Jeffrey M. Zirger,

Lead,

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